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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/584,982	04/02/2007	Robin Kurfurst	15675P620	2408
7590	11/26/2008		EXAMINER	
Blakely, Sokoloff, Taylor & Zafman 12400 Wilshire Boulevard, 7th floor Los Angeles, CA 90025		GIBBS, TERRA C		
		ART UNIT		PAPER NUMBER
		1635		
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		11/26/2008		PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>
	10/584,982	KURFURST ET AL.
	<b>Examiner</b>	<b>Art Unit</b>
	TERRA C. GIBBS	1635

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

1) Responsive to communication(s) filed on 31 October 2008.

2a) This action is **FINAL**.                            2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

4) Claim(s) 38 and 42-57 is/are pending in the application.

4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

5) Claim(s) \_\_\_\_\_ is/are allowed.

6) Claim(s) 38 and 42-57 is/are rejected.

7) Claim(s) \_\_\_\_\_ is/are objected to.

8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All    b) Some \* c) None of:

- Certified copies of the priority documents have been received.
- Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
- Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

1) <input type="checkbox"/> Notice of References Cited (PTO-892)	4) <input type="checkbox"/> Interview Summary (PTO-413)
2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)	Paper No(s)/Mail Date. _____ .
3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)	5) <input type="checkbox"/> Notice of Informal Patent Application
Paper No(s)/Mail Date _____ .	6) <input type="checkbox"/> Other: _____ .

## DETAILED ACTION

### ***Continued Examination Under 37 CFR 1.114***

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission mailed on October 31, 2008 has been entered.

Claims 22-37, 39-41, 58, and 59 have been canceled. Claims 38 and 57 have been amended.

Claims 38 and 42-57 are pending in the instant application.

Claims 38 and 42-57 have been examined on the merits.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

### ***Response to Arguments***

Applicant's Amendment and Response filed October 31, 2008 have been considered. Rejections and/or objections not reiterated from the previous Office Action mailed August 1, 2008 are hereby **withdrawn**. **Any arguments addressing said rejections and/or objections are moot.** The following rejections and/or objections are either newly applied or are reiterated and are the only rejections and/or objections presently applied to the instant application.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 38 and 42-57 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 95/02069 A1 ('069) (submitted and made of record on Applicant's Information Disclosure Statement filed November 20, 2006) as evidenced by Lazou et al. (submitted and made of record in the Office Action filed February 5, 2008).

Claim 38 is drawn to a method for depigmenting or bleaching human skin, body hair and/or head of a subject to lighten the color for purely cosmetic purposes comprising administering a cosmetic or topical pharmaceutical composition to the skin, body hair and/or hair of the head of said subject a composition comprising at least one oligonucleotide capable of specifically hybridizing with genes or gene products coding for protein kinase C beta-1. Claims 42-56 are dependent on claim 1 and include all the

limitations of claim 1 with the further limitations wherein said composition comprises at least one oligonucleotide capable of specifically hybridizing with any 5' to 3' regions, coding or non-coding region of genes coding for PKC beta-1; wherein said composition comprises SEQ ID NO:1; wherein said composition comprises chemical modifications including modified sugar moieties of 2'-O-fluoro substituents; wherein said composition comprises a phosphodiester groups; wherein the phosphodiester groups are replaced by phosphorothioate groups; wherein the phosphodiester groups are replaced by methylphosphonate groups; wherein said composition comprises a vector or plasmid; wherein said composition comprises one or more active agents, including anti-inflammatory agents; wherein the oligonucleotide represents 0.00001% to 10% of the total weight of the composition; and wherein said composition is presented in the form of an emulsion containing an oil. Claim 57 is drawn to a method for the treatment or the prevention of regional hyper-pigmentation by melanocyte hyperactivity such as idiopathic melasma, local hyper-pigmentation by benign melanocyte hyperactivity and proliferation such as pigmentary age spots, accidental hyper-pigmentation such as post-lesion healing in a subject in need thereof, comprising the topical application to the hyperpigmented skin areas of said subject a topical pharmaceutical composition comprising at least one oligonucleotide capable of specifically hybridizing with genes or gene products coding for protein kinase C beta-1.

*Determining the scope and contents of the prior art*

'069 teaches and claims a method of modulating the expression of PKC-beta in cells comprising contacting the cells with an oligonucleotide, said oligonucleotide being

specifically hybridizable with a PKC gene or PKC mRNA (see claims 37, 44, 45, and 48). '069 teaches that the methods of their invention are conducted *in vivo* (see page 12, lines 28-34) and that the inhibition of PKC expression is useful for the treatment of diseases, particularly hyperproliferative and inflammatory disorders (see page 12, lines 9-11). '069 teaches that the oligonucleotide is specifically hybridizable with a 5' untranslated region, coding region or 3' untranslated region (see claim 38). '069 teaches and claims that the oligonucleotide comprises intersugar linkages, including a phosphorothioate moiety (see claim 39). '069 also teaches that the oligonucleotide comprises a 2'-fluoro modification or a 2'-O-methyl modification (see claims 41 and 42). '069 also teaches and claims that the oligonucleotide is SEQ ID NO:28, where SEQ ID NO:28 is identical to SEQ ID NO:1 of Applicant's invention (see claim 49). '069 also teaches and claims a method of treating a condition associated with the expression of PKC-beta comprising administering to a mammal an oligonucleotide, said oligonucleotide being specifically hybridizable with a PKC gene or PKC mRNA, wherein the condition is a hyperproliferative disorder, including psoriasis or skin cancer (see claims 70-72, 76, 86, and 89, for example). '069 teaches that the oligonucleotide is specifically hybridizable with a 5' untranslated region, coding region or 3' untranslated region (see claim 77). '069 claims that the oligonucleotide comprises intersugar linkages, including a phosphorothioate moiety (see claim 78). '069 also teaches that the oligonucleotide comprises a 2'-fluoro modification or a 2'-O-methyl modification (see claims 80 and 81). '069 also teaches and claims that the oligonucleotide is SEQ ID NO:28, where SEQ ID NO:28 is identical to SEQ ID NO:1 of Applicant's invention (see

claim 90). '069 also teaches that the oligonucleotide compositions also include active ingredients such as anti-inflammatory agents (see page 18, lines 1-3) and oily based emulsifiers (see page 18, lines 14-24). '069 also teaches and claims that the oligonucleotide compositions of their invention are pharmaceutical compositions comprised in a pharmaceutically acceptable carrier (see claim 18) and are administered topically (see page 18, lines 6-13).

It is noted that '069 is silent as to whether or not their method of modulating the expression of PKC-beta in cells or method of treating a condition associated with the expression of PKC-beta specifically treats regional hyper-pigmentation by melanocyte hyperactivity such as idiopathic melasma, local hyper-pigmentation by benign melanocyte hyperactivity and proliferation such as pigmentary age spots, accidental hyper-pigmentation such as post-lesion healing as instantly claimed. However, it is the Examiner's position that the topical administration to the skin of an oligonucleotide being specifically hybridizable with a PKC gene or PKC mRNA as disclosed by '069 would inherently treat regional hyper-pigmentation by melanocyte hyperactivity such as idiopathic melasma, local hyper-pigmentation by benign melanocyte hyperactivity and proliferation such as pigmentary age spots, accidental hyper-pigmentation such as post-lesion healing, absent evidence to the contrary.

The burden of establishing whether the prior art method has the function of treating regional hyper-pigmentation by melanocyte hyperactivity such as idiopathic melasma, local hyper-pigmentation by benign melanocyte hyperactivity and proliferation such as pigmentary age spots, accidental hyper-pigmentation such as post-lesion

healing, under generally any assay conditions falls to Applicant. See MPEP 2112.01, “Where the claimed and prior art products are identical or substantially identical in structure or composition, or are produced by identical or substantially identical processes, a *prima facie* case of either anticipation or obviousness has been established. *In re Best*, 562 F.2d 1252, 1255, 195 USPQ 430, 433 (CCPA 1977). “When the PTO shows a sound basis for believing that the products of the applicant and the prior art are the same, the applicant has the burden of showing that they are not.” *In re Spada*, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990). Therefore, the *prima facie* case can be rebutted by evidence showing that the prior art products do not necessarily possess the characteristics of the claimed product. *In re Best*, 562 F.2d at 1255, 195 USPQ at 433.” See also MPEP 2112: “[T]he PTO can require an Applicant to prove that the prior art products do not necessarily or inherently possess the characteristics of his [her] claimed product.” The MPEP at 2112 citing *In re Fitzgerald* 205 USPQ 594. 596, (CCPA 1980), quoting *In re Best* 195 USPQ 430 as per above. Also, see *In re King*, 801 F.2d 1324, 1327, 231 USPQ 136, 139 (Fed. Cir. 1986). Therefore, it falls to Applicant to determine and provide evidence that the that the topical administration to the skin of an oligonucleotide being specifically hybridizable with a PKC gene or PKC mRNA as disclosed by ‘069 would or would not have the additional function of treating regional hyper-pigmentation by melanocyte hyperactivity such as idiopathic melasma, local hyper-pigmentation by benign melanocyte hyperactivity and proliferation such as pigmentary age spots, accidental hyper-pigmentation such as post-lesion healing as instantly claimed.

It is also noted that '069 does not necessarily mention that their method of modulating the expression of PKC-beta in cells as recited in claims 37-53 may be applied on the skin or hair of a human subject. However, one of ordinary skill in the art, upon reading the methods of claims 37-53, would immediately envision application to the skin or hair of a human subject since '069 at claims 72 and 76 contemplate methods of treating psoriasis and skin cancer, respectively, comprising contacting cells with an oligonucleotide that is specifically hybridizable with a PKC gene or PKC mRNA. Further, one of ordinary skill in the art would immediately envision specifically PKC-beta 1 since '069 also contemplates modulating the expression of PKC-beta, and specifically PKC-beta 1 (see claims 45, 48, 86, 89, and 90 and Table 3, for example). It is also noted that regarding a method of treating a condition associated with the expression of PKC-beta as recited in claims 70, 72, and 76, '069 does not necessarily mention which particular PKC isozyme is targeted. However, one of ordinary skill in the art, upon reading the methods of claims 70, 72, and 76, would immediately envision PKC-beta 1 since '069 contemplates this particular isozyme (see claims 86, 89, and 90 and Table 3, for example). It is further noted that regarding the method of claim 90, '069 does not necessarily mention which particular condition associated with the expression of PKC-beta is to be treated. However, one of ordinary skill in the art, upon reading the method of claim 90, would immediately envision depigmenting or bleaching human skin or treating regional hyper-pigmentation since these methods are inherent to the method step recited in claim 90 of '069 (as discussed below).

It is also noted that regarding claims 37-53 of '069, drawn to a method of

modulating the expression of PKC-beta in cells comprising contacting the cells with an oligonucleotide said oligonucleotide being specifically hybridizable with a PKC gene or PKC mRNA, '069 teaches that "modulation" means either an increase or decrease of PKC expression (see page 13, lines 12-14). It is further noted that '069 specifically teaches:

"Methods of treating conditions amendable to therapeutic intervention by modulating protein kinase C expression with an oligonucleotide specifically hybridizable with a PKC gene or mRNA are disclosed" (see Abstract)

"Aspects of the invention are directed to methods for...therapeutics of animals suspected of having a disease associated with PKC or one of its isozymes. Such methods comprise contacting the animal...with oligonucleotides in accordance with the invention in order to modulate the expression of PKC, to treat conditions associated with PKC" (see page 10, lines 3-10).

"Inhibition of PKC expression is expected to be useful for the treatment of disease, particularly hyperproliferative and inflammatory disorders" (see page 13, lines 9-11).

Given these disclosures, it is clear that the method recited in claims 37-53 of '069 are conducted *in vivo*.

It is also noted that '069 claims a method of treating a condition associated with the expression of PKC-beta comprising administering to a mammal an oligonucleotide said oligonucleotide being specifically hybridizable with a PKC gene or PKC mRNA, wherein the condition is a **hyperproliferative disorder**, including psoriasis, skin cancer, or inflammatory disorder (see claims 70, 72, 76, and page 13, lines 9-11) where psoriasis is an **inflammatory** skin condition characterized by an accelerated growth of skin cells and claim 57 of Applicant's invention specifically claims a method for the

treatment or the prevention of regional hyper-pigmentation by melanocyte hyperactivity such as idiopathic melasma, local hyper-pigmentation by benign melanocyte **hyperactivity** and **proliferation** such as pigmentary age spots, accidental hyper-pigmentation such as post-lesion healing.

*Ascertaining the differences between the prior art and the claims at issue*

‘069 is silent as to whether or not their method of modulating the expression of PKC-beta in cells or method of treating a condition associated with the expression of PKC-beta specifically depigments or bleaches human skin. However, it is the Examiner’s position that the topical administration to the skin of an oligonucleotide being specifically hybridizable with a PKC gene or PKC mRNA, including a PKC-beta 1 specific oligonucleotide, as disclosed by ‘069 would inherently depigment or bleach human skin, as evidenced by Lazou et al. who teach that **the topical administration of antisense oligonucleotides targeted to PKC-beta 1 lightens and whitens skin** (see Abstract and Table 1). Therefore, absent evidence to the contrary, the topical administration to the skin of an oligonucleotide being specifically hybridizable with a PKC-beta 1 as disclosed by ‘069 would inherently depigment or bleach human skin.

*Resolving the level of ordinary skill in the pertinent art*

The level of ordinary skill in the pertinent art is considered to be high, being a graduate student or post-doctoral fellow in a biological science.

*Considering objective evidence present in the application indicating obviousness or nonobviousness*

It would have been *prima facie* obvious to one of ordinary skill in the art, at the

time the invention was made, to devise a method for depigmenting or bleaching human skin comprising administering a cosmetic or topical pharmaceutical composition to the skin, body hair and/or hair of the head of said subject comprising at least one oligonucleotide capable of specifically hybridizing with genes or gene products coding for protein kinase C beta-1 using the teachings of '069 as evidenced by Lazou et al. It would have been *prima facie* obvious to one of ordinary skill in the art, at the time the invention was made, to devise a method for the treatment or the prevention of regional hyper-pigmentation by melanocyte hyperactivity such as idiopathic melasma, local hyper-pigmentation by benign melanocyte hyperactivity and proliferation such as pigmentary age spots, accidental hyper-pigmentation such as post-lesion healing in a subject in need thereof, comprising the topical application to the hyperpigmented skin areas of said subject of a topical pharmaceutical composition comprising at least one oligonucleotide capable of specifically hybridizing with genes or gene products coding for protein kinase C beta-1 using the teachings of '069.

One of ordinary skill in the art would have been motivated to devise a method for depigmenting or bleaching human skin comprising administering a cosmetic or topical pharmaceutical composition to the skin, body hair and/or hair of the head of said subject comprising at least one oligonucleotide capable of specifically hybridizing with genes or gene products coding for protein kinase C beta-1 since '069 taught that such a method could treat conditions associated with the expression of PKC-beta. One of ordinary skill in the art would have been motivated to devise a method for the treatment or the prevention of regional hyper-pigmentation by melanocyte hyperactivity such as

idiopathic melasma, local hyper-pigmentation by benign melanocyte hyperactivity and proliferation such as pigmentary age spots, accidental hyper-pigmentation such as post-lesion healing in a subject in need thereof, comprising the topical application to the hyperpigmented skin areas of said subject of a topical pharmaceutical composition comprising at least one oligonucleotide capable of specifically hybridizing with genes or gene products coding for protein kinase C beta-1 since '069 taught methods of treating a condition associated with the expression of PKC-beta, particularly PKC-beta 1.

One of ordinary skill in the art would have had a reasonable expectation of success of devising a method for depigmenting or bleaching human skin comprising administering a cosmetic or topical pharmaceutical composition to the skin, body hair and/or hair of the head of said subject a composition comprising at least one oligonucleotide capable of specifically hybridizing with genes or gene products coding for protein kinase C beta-1 because '069 taught the successful use and design of such a method for treating conditions associated with the expression of PKC-beta, particularly PKC-beta 1. One of ordinary skill in the art would have had a reasonable expectation of success of devising a method for the treatment or the prevention of regional hyper-pigmentation by melanocyte hyperactivity such as idiopathic melasma, local hyper-pigmentation by benign melanocyte hyperactivity and proliferation such as pigmentary age spots, accidental hyper-pigmentation such as post-lesion healing in a subject in need thereof, comprising the topical application to the hyperpigmented skin areas of said subject of a topical pharmaceutical composition comprising at least one oligonucleotide capable of specifically hybridizing with genes or gene products coding

for protein kinase C beta-1 because '069 taught the successful use and design of methods for treating a condition associated with the expression of PKC-beta.

In summary, because the methods recited in the prior art and Applicant's method for depigmenting or bleaching human skin recite the same method step, namely the application to a subject a composition comprising at least one oligonucleotide capable of specifically hybridizing with genes or gene products coding for protein kinase C beta-1, it is the Examiner's position that the methods steps recited in the prior art would inherently carry out the method step as claimed in Applicant's invention, as evidenced by Lazou et al., absent evidence to the contrary. That is, the method of modulating the expression of PKC-beta in cells comprising contacting the cells with an oligonucleotide said oligonucleotide being specifically hybridizable with a PKC-beta 1 and the method of treating a condition associated with the expression of PKC-beta comprising administering to a mammal an oligonucleotide said oligonucleotide being specifically hybridizable a PKC-beta 1 taught by '069 would inherently depigment or bleach human skin as instantly claimed in Applicant's invention, absent evidence to the contrary.

Furthermore, the method of modulating the expression of PKC-beta in cells comprising contacting the cells with an oligonucleotide said oligonucleotide being specifically hybridizable with a PKC-beta 1 and the method of treating a condition associated with the expression of PKC-beta comprising administering to a mammal an oligonucleotide, said oligonucleotide being specifically hybridizable a PKC-beta 1 taught by '069 would inherently treat or prevent regional hyper-pigmentation by melanocyte hyperactivity such as idiopathic melasma, local hyper-pigmentation by benign

melanocyte hyperactivity and proliferation such as pigmentary age spots, accidental hyper-pigmentation such as post-lesion healing in a subject in need thereof as instantly claimed in Applicant's invention, absent evidence to the contrary. Again, because the method steps in the prior art and the method steps of Applicant's invention are the exact same, the prior art methods would inherently carry out the functionality of Applicant's claimed invention, absent evidence to the contrary. See *In re Best*, 562 F.2d 1252, 1255, 195 USPQ 430, 433 (CCPA 1977) and *In re King*, 801 F.2d 1324, 1327, 231 USPQ 136, 139 (Fed. Cir. 1986).

Therefore, the invention would have been *prima facie* obvious to one of ordinary skill in the art at the time of filing.

### ***Conclusion***

No claims are allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Terra C. Gibbs whose telephone number is 571-272-0758. The examiner can normally be reached on 9 am - 5 pm M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James "Doug" Schultz can be reached on 571-272-0763. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent

Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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November 20, 2008  
/Terra Cotta Gibbs/

<b>Application Number</b> 	Application/Control No.	Applicant(s)/Patent under Reexamination
	10/584,982	KURFURST ET AL.
Examiner	Art Unit	
TERRA C. GIBBS	1635	